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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,401	07/18/2003	Craig A. Rosen	PZ020P2C1	6102

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HUMAN GENOME SCIENCES INC
INTELLECTUAL PROPERTY DEPT.
14200 SHADY GROVE ROAD
ROCKVILLE, MD 20850

EXAMINER	
ZEMAN, MARY K	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,401	ROSEN ET AL.	
	Examiner	Art Unit	
	Mary K. Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-33 and 48-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-33 and 48-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/5/05 has been entered.

Inventorship

In view of the papers filed 4/5/05, the inventorship in this nonprovisional application has been changed by the deletion of BIRSE, EBNER, HYAW, LaFLEUR, MOORE, NI, OLSEN, SHI, SOPPET, and WEI.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Response to Arguments

Applicant's arguments filed 4/5/05 have been fully considered but they are not persuasive.

Claims 24-33 and 48-57 are pending in this application. The response filed 4/5/05 did not amend the claims. The amendment to the title has been entered.

Claim Rejections - 35 USC § 101/112

Claims 24-33 and 48-57 remain rejected under 35 U.S.C. ə 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or a well established utility for the reasons set forth in the previous office action.

The rejected claims are drawn to polypeptides, or specific portions of SEQ ID NO: 145, or the protein from the related deposit HFVAB79. Fusion proteins, compositions comprising carriers, and product-by process claims are included.

Applicant's arguments filed 4/5/05 have been carefully considered, but are not deemed persuasive. Previous office actions have clearly set forth the facts of the disclosure regarding SEQ ID NO: 145 in the specification.

Applicant argues that the "only similar polypeptides necessary" for the establishment of a well-established utility are ones useful as tissue specific markers for cancer. Applicant has failed to demonstrate any sequence similarity or structural similarity between SEQ ID NO: 145 and any proteins known for the diagnosis, detection, prevention and/or treatment which are described in the specification or were well known at the art at the time of priority. The fact that they are all proteins is not sufficient. All of the references cited by Applicant in the response are to differing proteins having differing sequences, differing structures, and differing bodies of knowledge in the scientific community. Each protein cited appears to have been the subject of much study and analysis which is not set forth in the specification for the disclosed and claimed SEQ ID NO: 145.

Applicant asserts that the disclosure of an expression pattern is the same as an activity. This is not persuasive. An activity is something the protein does in the cell in which is it expressed. Catalyzing an enzymatic reaction is one example. The specification, as filed, fails to identify any activity for the claimed polypeptides.

Applicant questions which aspect of the asserted utilities fail to meet the standard. As has been set forth previously, the polypeptide of SEQ ID NO: 145 does not have a specific, substantial and credible utility, and does not have a well-established utility according to 35 USC 101.

Applicant argues that the expression pattern of the claimed polypeptide in a given tissue alone supports the asserted utility of diagnosis, detection, prevention and/or treatment of liver disorders. This is not persuasive, as the specification fails to provide any evidence that SEQ ID NO: 145 is related to any disorder or the liver.

Applicant argues the post-filing art supports the asserted utilities for the claimed sequence, however, as set forth previously, these publications set forth experiments, data and procedures that go beyond those described in the specification. The specification does not set forth the experiments of Smith, or Roult that led to their conclusions.

Applicant argues that the polypeptides can be used to generate antibodies that may have a further use. This is not persuasive. Further research utility is not deemed to meet the standard of specific, substantial and credible. There is no disclosed or real world utility associated with the claimed protein. Further experimentation is necessary to attribute a utility to the claimed protein. See Brenner v. Manson, 383 U.S. 519, 535–36, 148 USPQ 689, 696 (1966) (noting that "Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing", and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.").

Applicant correctly notes that the final rejection contained the body of the original rejection for completeness of the record as to the teaching of the specification.

Applicant further argues the propriety of the associated 112, first paragraph rejection. This is not persuasive, as the action clearly sets forth a proper rejection under 35 USC 101.

As set forth previously, the claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a real world use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

The specification identifies SEQ ID NO: 145, the elected polypeptide sequence, as being related to "gene 7" at pages 28-30. SEQ ID NO: 145 is also referenced in the table at page 276. At pages 28-30, the specification asserts that the polypeptide sequence encoded by "gene 7" is expressed primarily in the liver and testes.

At pages 28-30 the specification lists a variety of potential activities and tissue "specificities" that may be related to the elected sequence. Activities and specificities for the DNA and/or encoded protein listed in this section include: hepatic, endocrine and reproductive disorders, as well as immune system and hematopoetic system disorders. At no point is the specifically elected sequence tested for any of the listed associations, activities or expression patterns. At no point is a diagnostic test for any disease developed such that the elected sequence is shown to be linked diagnostically to a particular disease. Each of the above activities is very

different, and they are substantially non-overlapping. One of skill in the art would not readily be able to determine a use for the claimed sequence upon reading the specification.

At pages 29-30, the specification sets forth a laundry list of potential uses for any protein involved in cell growth and differentiation, including "detection, treatment, and./or prevention of hepatoblastoma, jaundice, hepatitis or liver metabolic diseases and conditions that are attributable to the differentiation of hepatocyte progenitor cells" without specifically linking the claimed protein to any particular type of disorder, activation pathway or other activity. The list of potential uses include the disparate categories of testicular function, other reproductive disorders, inflammatory disorders, cancer, as well as the categories of "hypoproliferative disorders" and "Infectious diseases". Each of these categories of disease have widely varying etiology, causes, and treatments, and the specification provides no particular evidence linking the claimed protein to any particular disease, or even class of diseases.

The laundry list of potential activities pointed to by Applicant all are general in nature, many are conflicting, many have widely varying causes or effects such that upon reading the specification, one of skill in the art would not be readily able to determine a specific substantial and credible utility for the claimed polypeptides.

The specification was further probed for information as to a specific substantial and credible utility for the claimed peptide. At page 276, in the table, SEQ ID NO: 145 is identified as being encoded by SEQ ID NO: 17. The table asserts that the polypeptide has a signal sequence beginning with amino acid 1, and ending with amino acid 15, and asserts that the secreted portion would be from amino acids 16-194. This information was all generated by computer analysis and has not been validated by producing the polypeptide in vitro and observing cleavage and secretion of the actual sequence. No such experiments are set forth in the specification as filed. No particular activities or functions are specifically linked to any form of the polypeptides being claimed.

Claims 24-33 and 48-57 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD can be reached on (571) 272 0718. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

MARY K. ZEMAN
PRIMARY EXAMINER
AU 1631
6/17/05